Digital Transformation in Healthcare

Challenges and Opportunities in Policy and Management

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re:search is a digital policy paper series that aims to disseminate the findings of research sponsored by Bocconi University in a way that is accessible to both policy-makers and the wider public. Its purpose is to bridge the gap between the academic and policy worlds, while informing decision-making and public discourse.

Introduction

Thanks to a wide range of technologies, including computing platforms, connectivity, software, applications (apps), artificial intelligence algorithms, and sensors, digital health is widely recognized as a key force in improving healthcare. Its applications range from digital health apps that support patient self-management to generative artificial intelligence algorithms that help healthcare professionals diagnose and optimize treatment, from telemedicine platforms that enable virtual consultations to health information systems that streamline data collection and exchange.

Prior to the onset of the COVID-19 pandemic, the healthcare sector had lagged behind other industries in digital innovation, as healthcare organizations struggled to consistently adopt **digital health technologies (DHTs)** to electronically exchange data and redefine care processes. However, the pandemic served as a catalyst, exposing the weaknesses of traditional healthcare delivery and prompting countries around the world to embrace DHTs and introduce virtual care components.

Although many countries have accelerated the adoption of DHTs, true **digital transformation** goes beyond mere technological digitization, which should be viewed as a means to an end. Proper digital transformation involves the consistent assimilation of DHTs into organizational, managerial, and professional practices that are aligned with user needs to drive performance improvements and ultimately improve patients' health outcomes.

Closing this gap will require the simultaneous achievement of several conditions, with **three primary layers of action** that combine initiatives stemming from healthcare professionals and managers with top-down strategies enacted by governments. First, insights are critical to enriching **patient-physician interaction**, recognizing the increasing digital connectivity of individuals and their desire for active participation in decision-making and healthcare delivery processes. At the same time, **new management practices**, organizational responsibilities, and enhanced workforce competencies are essential at the **service delivery level**. Lastly, a series of **policy initiatives** and clear regulatory frameworks are needed to facilitate market access for innovative yet safe and effective DHTs and to incentivize their uptake by healthcare organizations and professionals.

In this ebook, we present the work carried out by the **Centre for Research on Health and Social Care Management (CERGAS)** at Bocconi University, addressing each layer of action. Through a variety of research projects and educational initiatives, we aim to support a diverse mix of stakeholders involved in the digital transformation process and to encourage fruitful dialogue and collaboration among them. Consistently, our recommendations are addressed to the entire spectrum of stakeholders involved, with the goal of identifying critical areas of action and ultimately advancing the digital transformation of healthcare.

The digital transformation of the patient-physician relationship and of clinical decision-making

Over the past decade, the adoption of digital tools, architectures, and innovations has grown exponentially across healthcare systems at all levels of care. The adoption of new digital health technologies (DHTs) has the potential to empower healthcare professionals (HCPs) to deliver better care and patients to become more active participants in their own care. As a result, DHTs might transform care as we know it, reshaping the experiences of patients, HCPs, and the relationship between them.

From the **patient's perspective**, the entire care experience can be transformed depending on the level and purpose of adoption of DHTs. These tools can contribute to the proliferation of more patient-centered care models by providing patients with convenient access to medical information, enabling remote monitoring, and promoting patient engagement in self-management and well-being through the systematic provision of data about their health status, their perception of the quality of care received and of the relationship with HCPs.
From the **HCP's perspective**, DHTs can revolutionize the approach to patient care by facilitating collaboration across medical specialties and different healthcare professions, by enhancing the accuracy of clinical decision-making, and by streamlining more routine tasks, thereby freeing up time for more complex clinical activities. Ultimately, DHTs are expected to reshape HCPs' job and task profiles, while improving decision-making processes by incorporating novel sources of diverse data that are mostly neglected in current clinical practice.
These elements of change, in turn, can affect the **relationship between patients and HCPs**. The frequency and nature of interactions can be reorganized through DHTs. For example, instant messaging can be used to quickly confirm medical information such as medication dosages, or images can be sent to demonstrate progress in a surgical care pathway. The content of interactions is also evolving, as tools such as digital health apps can activate a feedback loop between patients and HCPs, helping them to send, receive, process, and discuss information. For example, the patient-physician relationship can be strengthened by supplementing in-person consultations with additional communication channels, depending on individual attitudes, exposure, perceptions, and use of DHTs. Conversely, it can be weakened, particularly if patients or HCPs are resistant to adopting new technologies or distrustful of a particular innovation.

Insights from our research
Projects conducted at CERGAS are helping to improve our understanding of how DHTs are changing the way patients and HCPs approach each step of the healthcare delivery process and interact with each other. The results of these projects also alert us

to the conditions needed to guarantee that these changes drive a positive digital transformation of healthcare delivery.

First, the results of these projects indicate that, for DHTs to be truly transformative, their development and adoption must align with the **expectations of patients and HCPs about the overall care experience**. Additionally, processes to capture these expectations and develop trust around DHTs must be put in place.

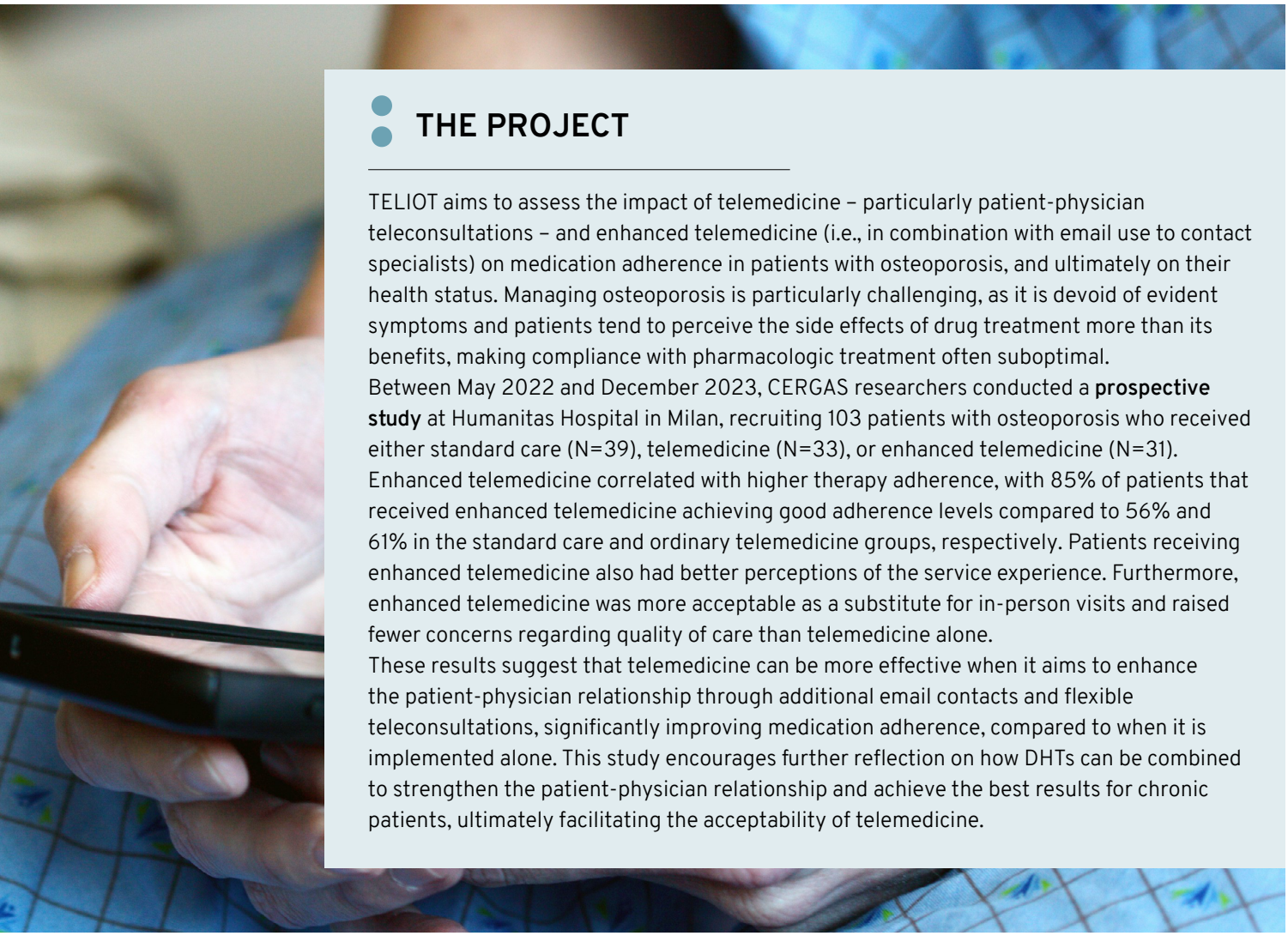
In the development of DHTs, for instance, the input of patients and HCPs is essential to guarantee that these technologies are not only more acceptable, but also impactful on the care delivered. CERGAS has extensive experience in supporting the development of mobile apps through **participatory design approaches**, as demonstrated in projects such as POWER, an observational study on an app evaluating the relationship between physical activity levels and bleeding in patients with hemophilia A, or LuCApp, a randomized controlled trial that tested the impact of a mobile app based on real-time monitoring and management of symptoms on the quality of life and anxiety levels of patients with lung cancer. In both cases, the functionalities of the apps included in these studies were designed in collaboration with patients and included the possibility to collect data directly from patients through patient-reported outcome measures (PROMs). The TELIOT project, a study funded by Fondazione Cariplo to assess the impact of telemedicine enhanced by the combination with an app on osteoporotic patients' compliance to drug therapy, showed that an initial participatory design approach in collaboration with patients and HCPs might not be enough to guarantee full usability in real healthcare settings. The study showed that technology developers might need to continuously refine DHTs and apps, even after their introduction in clinical practice, and to guarantee a reliable "customer service" to solve doubts and issues with the DHT, thereby maintaining a good degree of trust over time.

The other conducive condition to make DHTs more acceptable to patients and HCPs, as shown by CERGAS' projects, is that they facilitate or improve the **communication between patients and HCPs**, allowing to better align the expectations of the two parts about the care process. For instance, CERGAS is currently participating in CINDERELLA, a project funded by Horizon Europe, based on the idea that the satisfaction of breast cancer patients with surgery can be increased by improving

the communication between patients and their surgeons about the final aesthetic outcomes of breast cancer surgery through the use of an AI-powered web application. In the TELIOT project, instead, an app or email is combined with teleconsultation, making it easier for patients with osteoporosis who start their drug therapy to contact bone specialists outside of the fixed appointments set for the follow-up. The project shows how indeed this combination of DHTs can effectively increase adherence to therapy.

After the design stage, other strategies are fundamental to maximize acceptance of DHTs among HCPs and patients. For HCPs, initial training on the technology, typically provided by either internal developers or external vendors, reduces barriers to access and enhances confidence. Peer-to-peer knowledge sharing among HCPs in later stages has proven equally valuable in driving adoption. For patients, seamless interaction with DHTs, achieved not only through participatory design but also via extensive usability testing, is generally a prerequisite for successful and sustained use. In breast cancer research initiatives, patient advocates have emphasized the importance of early engagement and the level of prior scientific evidence behind a given innovation.

However, it is even more important to communicate and demonstrate with facts why certain digitally enabled interventions are useful, thereby building further trust in



THE PROJECT

TELIOT aims to assess the impact of telemedicine – particularly patient-physician teleconsultations – and enhanced telemedicine (i.e., in combination with email use to contact specialists) on medication adherence in patients with osteoporosis, and ultimately on their health status. Managing osteoporosis is particularly challenging, as it is devoid of evident symptoms and patients tend to perceive the side effects of drug treatment more than its benefits, making compliance with pharmacologic treatment often suboptimal.

Between May 2022 and December 2023, CERGAS researchers conducted a **prospective study** at Humanitas Hospital in Milan, recruiting 103 patients with osteoporosis who received either standard care (N=39), telemedicine (N=33), or enhanced telemedicine (N=31).

Enhanced telemedicine correlated with higher therapy adherence, with 85% of patients that received enhanced telemedicine achieving good adherence levels compared to 56% and 61% in the standard care and ordinary telemedicine groups, respectively. Patients receiving enhanced telemedicine also had better perceptions of the service experience. Furthermore, enhanced telemedicine was more acceptable as a substitute for in-person visits and raised fewer concerns regarding quality of care than telemedicine alone.

These results suggest that telemedicine can be more effective when it aims to enhance the patient-physician relationship through additional email contacts and flexible teleconsultations, significantly improving medication adherence, compared to when it is implemented alone. This study encourages further reflection on how DHTs can be combined to strengthen the patient-physician relationship and achieve the best results for chronic patients, ultimately facilitating the acceptability of telemedicine.

technologies backed by solid research. The more actively patients or HCPs engage with DHTs and can observe their value, the more likely they are to use them regularly in their care, leading to higher levels of satisfaction. A study by CERGAS at the Rheumatology Unit of ASST Niguarda Hospital in Milan found that previous telehealth users tended to expect fewer but more realistic benefits from telehealth experiences than non-users and were more likely to participate in future telehealth projects.

In addition to deliberate strategies to foster trust in DHTs, **individual and group perceptions of the potential of DHTs** inevitably influence the use of digital technologies by both HCPs and patients. These perceptions may be influenced by intrinsic cultural aspects stemming from prior knowledge of a particular disease or care model. For example, patients with HIV appear to appreciate the use of DHTs to interact with their clinicians, as these can ensure greater privacy and less invasive contact, as demonstrated in the Aids Plan Regional Implementation (APRI) project, in which CERGAS conducted a survey with 600 patients with HIV. Chronic patients accustomed to face-to-face interactions with specialists may, instead, express concerns about transitioning to digitally powered care pathways.

The ShareView project highlighted a multitude of additional factors beyond the availability of DHTs that facilitate the adoption of shared decision-making. The video summarizes the overall findings of the project.

Several other factors may shape individual perceptions, including age, level of digital skills, attitudes towards technology, information availability, prior experience with digital technologies, and outcomes of digital care delivery. The TELIOT project demonstrated an overall good level of acceptability of teleconsultation among patients with osteoporosis, independently from their age, low level of digital skills and absence of support at home in using the telemedicine platform. Yet, other factors seem to detract from this overall good level of acceptability. In particular, patients diagnosed with osteoporosis since longer were more hesitant about substituting in-presence visits with teleconsultations and expressed greater concern about the quality of the relationship with their specialists when digitally mediated. This indicates that the most salient factors impacting individual perceptions of DHTs might vary across diseases, groups of patients, and even over time.

Once integrated into practice, digital technologies can have, on the one hand, a significant **impact on clinical decision-making**, which is expected to achieve higher levels of accuracy through decision support provided to HCPs. For example, artificial intelligence (AI) algorithms can now reliably analyze large datasets to support clinical decisions, including tasks such as determining appropriate treatment dosages or identifying patients at high risk of deterioration.

DHTs may also facilitate the **shift to shared decision-making** between clinicians and patients. Notably, digital sources, whether publicly available or provided directly to patients, play a crucial role in reducing information asymmetry between patients and clinicians. As patients increasingly seek to play an active role in decisions about their health, DHTs offer opportunities such as suggesting equally viable treatment options based on patient preferences, utilizing synthetic information such as AI-generated estimates for informed decision-making, and aligning patient expectations by realistically reproducing treatment outcomes. However, technologies cannot achieve this on their own. A scoping review conducted by CERGAS researchers as part of ShareView, a project to support shared decision-making and communication in patients with metastatic breast cancer, highlighted a multitude of additional factors beyond the availability of DHTs that facilitate the adoption of shared decision-making. These include clinical team attitudes and knowledge, organizational support such as designated staff, training and educational materials, and regulatory requirements.

On top of influencing decision-making processes, DHTs can impact **the experience with delivering care of HCPs**,

influencing service models, daily routines, interprofessional coordination, gatekeeping, and the cost of care. For example, the introduction of new DHTs might either shorten or lengthen the time needed for consultations, prompting consideration of opportunity costs, and allowing for the incorporation of new routines into the daily agenda of HCPs.

Given all these possible impacts linked to their introduction, the **implementation of DHTs** in routine clinical practice needs to be constantly monitored to understand the way HCPs and patients perceive them. In general, consolidated scales such as the Mobile App Usability Questionnaire (MAUQ) or the Mobile Application Rating Scale (MARS) can be used to observe the perceived usability of mobile apps, both before and possibly after their adoption.

Furthermore, on the side of HCPs, a variety of aspects can be assessed through interviews, diaries, and focus groups. CERGAS researchers currently involved in the AI4Lungs project, an EU project piloting an AI-based tool to stratify patients with lung cancer or severe respiratory disease, have recently devised a new tool to collect data from HCPs about their perceptions of the AI-based DHT before and while implementing it in clinical practice.

With respect to patients, especially if they are active users of the DHT, measuring acceptance of the new technology already during the piloting phase is key to taking timely corrective action. Besides assessing usability, the perspective of patients can also be captured by collecting **patient-reported outcome and experience measures (PROMs and PREMs)** over time. These measures provide immediate feedback on how patients perceive the impact of DHTs on their care process and ultimately their health. As the delivery of care through DHTs aims to enhance the personalization of care, these measures offer the opportunity to gather information on which features of DHTs, or their combination, have the potential to be most responsive to specific patient needs.

In conclusion, the research projects conducted by CERGAS emphasize the need for HCPs and patients to actively steer the progressive introduction of DHTs in a way that benefits both parties and improves their relationship.

KEY MESSAGES TO PATIENTS

MISTRUST CAN BE VERY COSTLY

Trust the logic behind testing and adopting DHTs

EXPERIMENTATION AS ACTIVE SCIENCE

If you are comfortable with the idea of using DHTs, ask questions and participate in experimenting with such technologies

MAKE EVERY WORD COUNT

Whether in experimentation or routine, your feedback is a valuable foundation on which to build new DHTs and generate a real digital transformation of care

Remember: DHTs are here to improve your healthcare experience

KEY MESSAGES TO HCPS

IMPLEMENTATION MODE "ON"

Embrace the "implementation mode": joining new initiatives enables the testing of different digital possibilities, necessitating collaboration beyond patients alone

ASSESS, EVALUATE, IMPROVE…AND REPEAT

Collecting real-world data about how DHTs work is a necessary condition for identifying what works, for whom, and under what circumstances, and what is simply not useful

NETWORK IS NET WORTH

Feel part of a network and nurture the information within it: digital developers benefit from your feedback and from insights collected from patients

Remember: DHTs need to be built on evidence, and this will happen through your commitment

The digital transformation of healthcare organizations and services

Over the past few decades, healthcare organizations have undergone significant changes through the integration of digital health technologies (DHTs). This process of digital transformation involves a number of innovations, including the transition from paper-based medical records to electronic health records (EHRs), the widespread adoption of telemedicine for remote patient access and monitoring, and, more recently, the incorporation of AI-based tools and decision support systems. The adoption and seamless integration of these technologies, along with the establishment of multi-channel interactions between healthcare providers and patients, have the potential to revolutionize healthcare delivery. This requires service design or redesign and the development of an integrated and synergistic offering of services. As a result, the simultaneous and effective management of technological, service, organizational and strategic aspects engendered by DHTs becomes critical for healthcare managers and organizations.

From a **technology perspective**, adopting new digital innovations requires healthcare organizations to make complex decisions about platform and software selection and procurement. It also involves integrating and managing information flows, ensuring proper data integration, and providing patients with the necessary self-monitoring and communication devices, as well as equipping HCPs with monitoring and case management tools.

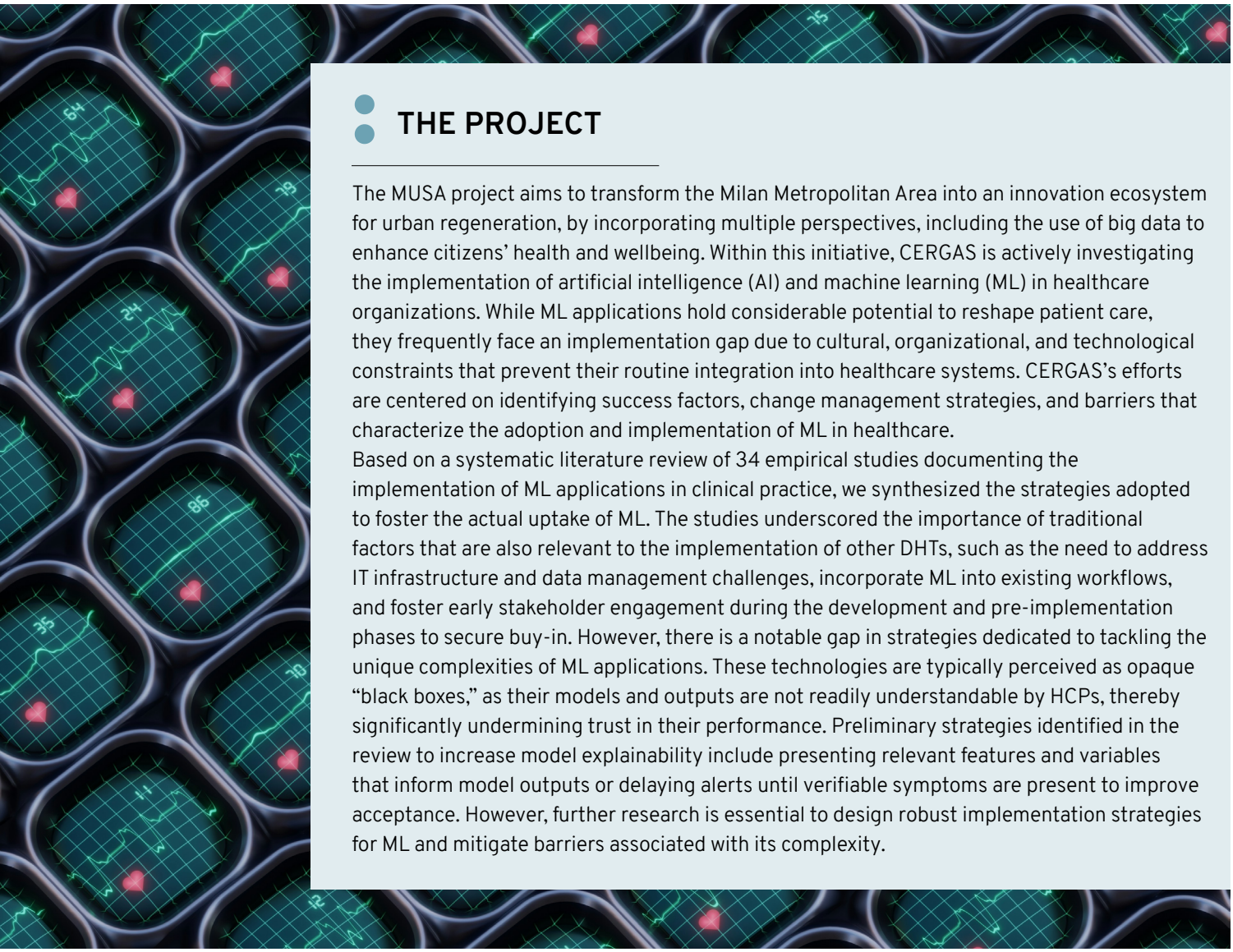
From a **service perspective**, it is imperative to conduct an analysis of patient characteristics and needs in order to effectively target different patient groups and identify the most appropriate digital and/or in-person services for their needs. Notably, not all digital tools are universally suitable for patients with different diseases, conditions, preferences, and attitudes. Therefore, careful attention must be paid from the ideation phase through development, design, and embedding of DHTs into service models.

From an **organizational and strategic perspective**, implementing DTHs requires a reorganization of resources and workflows to accommodate and sustain the related service innovations. This includes redefining responsibilities and roles, ensuring full fungibility of services, reconfiguring back-office and clinical operations, fostering collaboration with other health and social services, and adjusting leadership styles and chains of accountability within healthcare organizations or units. All these factors collectively influence the strategic positioning of healthcare organizations during their digital transition.

Insights from our research

The projects conducted at CERGAS are at the forefront of advancing our understanding of the transformative impact of DHTs on healthcare organizations.

Established in 2020, the **LIFT Lab** is CERGAS's life science and biotech lab aimed at investigating the increasing convergence of life sciences and digital technologies. Through the LIFT Radar, the LIFT Lab provides an important contribution to this field. In today's rapidly evolving technological landscape, healthcare managers responsible for **making strategic decisions on digital technology investments** often face exaggerated expectations fueled by the media, industry, and the public. To mitigate this "hype effect," the LIFT Radar supports healthcare and life sciences managers in making strategic decisions about DHTs by employing a structured three-step process that ensures thorough and balanced evaluations. The process starts with the scouting phase, which involves extensive mapping of DHTs through scientific and grey literature, providing the foundational knowledge required to comprehend the current discourse surrounding DHTs in health care. Following this, the taxonomy analysis categorizes each technology according to trends, applications, and features, defining their nature and scope. The final stage (assessment) evaluates DHTs across three primary dimensions: "distance", "impact", and "speed". This multifaceted evaluation allows to understand a technology's readiness, its potential effect upon adoption, and



THE PROJECT

The MUSA project aims to transform the Milan Metropolitan Area into an innovation ecosystem for urban regeneration, by incorporating multiple perspectives, including the use of big data to enhance citizens' health and wellbeing. Within this initiative, CERGAS is actively investigating the implementation of artificial intelligence (AI) and machine learning (ML) in healthcare organizations. While ML applications hold considerable potential to reshape patient care, they frequently face an implementation gap due to cultural, organizational, and technological constraints that prevent their routine integration into healthcare systems. CERGAS's efforts are centered on identifying success factors, change management strategies, and barriers that characterize the adoption and implementation of ML in healthcare.

Based on a systematic literature review of 34 empirical studies documenting the implementation of ML applications in clinical practice, we synthesized the strategies adopted to foster the actual uptake of ML. The studies underscored the importance of traditional factors that are also relevant to the implementation of other DHTs, such as the need to address IT infrastructure and data management challenges, incorporate ML into existing workflows, and foster early stakeholder engagement during the development and pre-implementation phases to secure buy-in. However, there is a notable gap in strategies dedicated to tackling the unique complexities of ML applications. These technologies are typically perceived as opaque "black boxes," as their models and outputs are not readily understandable by HCPs, thereby significantly undermining trust in their performance. Preliminary strategies identified in the review to increase model explainability include presenting relevant features and variables that inform model outputs or delaying alerts until verifiable symptoms are present to improve acceptance. However, further research is essential to design robust implementation strategies for ML and mitigate barriers associated with its complexity.

its expected evolution over time. Through this systematic approach, the LIFT Radar provides healthcare managers with the insights needed to navigate the complex landscape of DHTs, prioritize investments, and make informed strategic decisions within their own organizations.

After identifying the DHTs that are strategic for implementation, management choices are necessary to reorganize workflows and care pathways accordingly. The successful implementation of DHTs can lead to significant **gains in effectiveness and efficiency**, including time savings and error reduction, thereby improving the quality of care within healthcare organizations. DHTs and digital service platforms can also work as **integration tools**, connecting different settings, professionals, and phases of care. However, these advancements can only be achieved through substantial service redesign and organizational innovation. With the recognition of digital transformation as a key pillar for reforming healthcare systems, significant resources have been allocated to support digital transformation processes, including the centralized acquisition or development of digital platforms, integration systems, and devices.

In this context, CERGAS actively participates in Sanità Digitale, a partnership project funded by the NextGenerationEU program and the Italian National Recovery and Resilience Plan. This initiative supports Italian regions and healthcare organizations in the design and implementation of digital development projects across several healthcare domains. Many digital transformation initiatives are underway in areas such as primary and community care, telemedicine services, transitional care, laboratories, and a variety of administrative processes like booking systems, electronic patient records, and waiting list management tools. In one such project, in collaboration with the Veneto Region, CERGAS is supporting the design and implementation of an integrated community care health information system. This system aims to consolidate data from all community-level activities across the entire regional territory in a standardized and homogenous manner. To inform this design, CERGAS researchers have elaborated an overall **framework** to rethink the delivery of health and social services by healthcare organizations, leveraging the potential unlocked by DHTs. The framework outlines the main design principles and touchpoints to be considered in the development of such health information system.

Until recently, and especially during the Covid-19 pandemic, most digital transformation initiatives were bottom-up efforts promoted by HCPs. Now, the rapid adoption of DHTs inevitably requires a management-driven approach to actively steer change. For this to happen, healthcare managers need to create and spread a new digital culture, govern the complex coexistence of digital and traditional in-person care services, and elaborate processes for the involvement of all HCPs, who often work in different healthcare settings. Ultimately, the successful implementation of digital technologies requires the development and introduction of **effective change management strategies** by healthcare managers. Change management benefits from a favorable organizational climate and involves the stages of preparing for change, implementing change, and reinforcing change. Whether introducing a novel telemonitoring service, an AI-based decision support system, or brand-new digital therapeutics, healthcare managers need to create the conditions for change through a variety of operational and strategic practices. These may include conducting a needs assessment, creating a plan, identifying champions among HCPs, developing, and communicating a clear vision, recognizing successes, and continuously evaluating and monitoring change. In the case of DHTs, this might also entail understanding the acceptability of DHTs to patients and HCPs alike. For example, in a study on the implementation of a telemedicine service through an app that collects patient-reported outcomes in the rheumatology unit of Niguarda hospital in Milan, CERGAS researchers found

The framework, developed by CERGAS researchers, outlines the main design principles and touchpoints to be considered in the development of an integrated community care health information system. For more information, see the paper linked above.

The eLMIS & eIR project highlighted that greater use of electronic tools could improve the management of immunization programs. However, it also warned of several shortcomings that may limit the actual delivery of expected results. The video illustrates these findings.

that structured ways to involve patients in shaping the service were necessary to guarantee a good adoption of the DHT. Together with the incremental introduction of additional functions of the telemedicine service, these strategies were crucial for successful implementation.

Managerial change efforts must be even more decisive as organizations experiment with advanced technologies based on AI and machine learning (ML), which present unique complexities due to their opacity, as well as ethical and security implications. To address these challenges, CERGAS is participating in the MUSA (Multilayered Urban Sustainability Action) partnership project funded by NextGenerationEU, the program designed to boost recovery in the European Union. One task of this project is specifically dedicated to identifying the operational processes and strategies adopted by healthcare organizations to successfully implement AI and ML-based applications.

At the same time, **organizational structures are evolving** as new organizational units and departments are established to govern change. This evolution is leading to the emergence of new professional roles, such as telemedicine managers and key accounts, digital transformation officers, or data scientists for AI. Chief Information Officers (CIOs) play a pivotal role in this process, working closely with the C-suite and orchestrating the entire digital transformation journey within organizations. A study published in 2023 in the OASI Report, the Observatory on Healthcare Organizations and Policies in Italy published annually by CERGAS, revealed a variety of organizational models for telemedicine services adopted by healthcare organizations in the Italian NHS. These models not only show significant differences in terms of maturity, but they also present a range of alternatives that can be more or less suitable for each context, depending on the institutional and service arrangements in place.

The availability and effective management of valuable, real-time data is critical to the successful initiation of digitalization, enabling a **data-driven healthcare paradigm**. Tools like electronic health records (EHRs), electronic immunization registries, and logistics management information systems can streamline processes, decrease redundancies, and provide a basis for enhanced decision-making by healthcare managers. CERGAS researchers have explored the value of these systems across a variety of health settings, including nursing homes, and healthcare systems, extending their scope to developing economies as well. As for the former, a comprehensive analysis of over one hundred nursing homes in Italy that adopted the same EHR at a mature stage of digitalization confirmed substantial benefits in terms of improved care processes, reduced medical errors, and facilitated collaboration among HCPs. Concurrently, upon the request by the Bill and Melinda Gates Foundation (BMGF), the World Health Organization (WHO) and Gavi, the Vaccine Alliance, CERGAS researchers conducted the electronic Logistic Management Information Systems (eLMIS) and electronic Immunization Registries (EIR) project. This multi-country evaluation in four **low and middle-income countries** (Guinea, Honduras, Rwanda, and Tanzania) aimed to provide evidence on the impact of introducing and scaling up electronic immunization registries and electronic logistics management information systems for vaccines. The project highlighted that greater use of electronic tools could improve the management of immunization programs. However, it also warned of several shortcomings that may limit the actual delivery of expected results, suggesting the uptake of adaptive learning through monitoring and evaluation to facilitate prompt course corrections along the implementation path.

Overall, CERGAS research projects provide healthcare managers with evidence on the different nuances of the implementation of DHTs within their organizations. While recognizing that a one-size-fits-all approach is ineffective, as different implementation strategies and resources may be needed for different DHTs, our work emphasizes lessons and insights that can be broadly applied to a variety of healthcare contexts.

KEY MESSAGES TO HEALTHCARE MANAGERS

THINK STRATEGICALLY OF DHTs	Identify how DHTs can uniquely contribute to achieving organizational goals and create a course of action that leads to desired results
MANAGING CHANGE BEFORE DIGITAL CHANGES YOU	Long-term sustainability of DHTs and a digital transformation requires effective change management strategies and processes
NEW RULES, NEW ROLES	Consider the competencies needed and be prepared to identify new roles and responsibilities to manage change
IN DATA WE TRUST	Ensure data quality and standardization: improvements in decision making are only as good as the data on which they are based
JUST MEASURE IT!	To measure is to know: if you cannot measure something, you cannot improve it. Have metrics, collect data, and be prepared to evaluate the impact of DHTs and identify what is working and for whom, and what is not
TODAY'S INVESTMENT, TOMORROW'S VALUE	Keep in mind that adopting DHTs is an investment that may not yield immediate benefits and requires time for its advantages to become manifest. A multidimensional assessment is essential to weigh all potential benefits that will eventually be realized

Remember: DHTs should primarily support healthcare organizations in improving the delivery of healthcare

Regulation and assessment procedures of digital health technologies shaping digital transformation

Digital health technologies (DHTs) are widely recognized as an invaluable resource for creating new opportunities for healthcare professionals (HCPs) and patients, but also as potentially contributing to the financial sustainability of healthcare systems. However, DHTs must be carefully assessed and regulated to fully realize their potential and be integrated into standard care, ensuring equitable access to quality digital health for all citizens. To date, the lack of robust assessment procedures and clear regulatory and market access pathways has been a barrier to the rapid adoption of DHTs.

Decision-makers face **significant challenges** in defining requirements and processes for granting access to DHTs due to their unique characteristics compared to other types of healthcare technologies, such as pharmaceuticals and medical devices, for which regulatory and assessment models have long been established. Concurrently, it is challenging for policy-makers to keep pace with constant technological innovation as the frontiers of DHTs continue to advance.

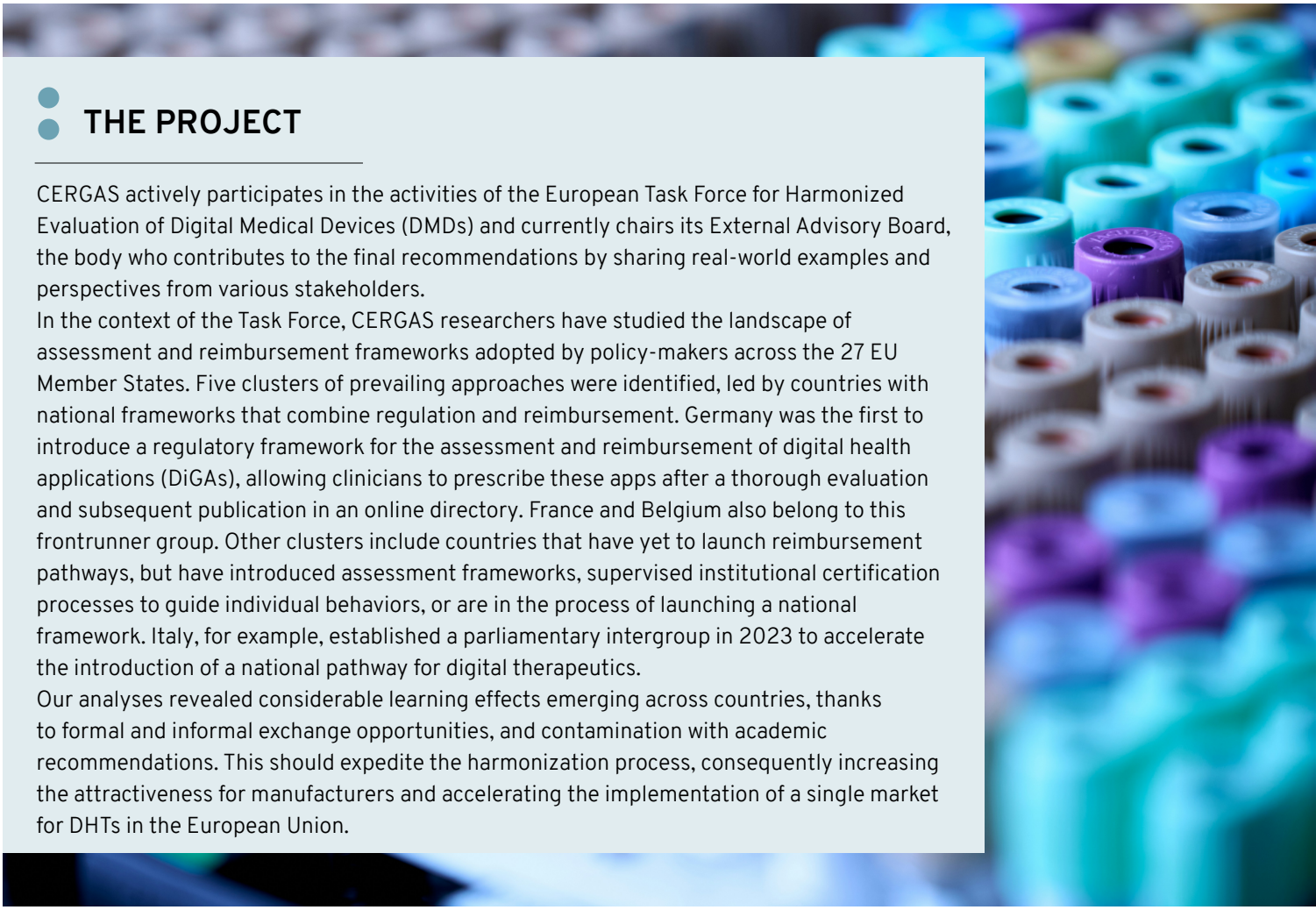
Limited market predictability has inevitably affected the decisions of investors, manufacturers, and innovators. Affected by unpredictable regulatory requirements and unclear guidance on the level of evidence necessary to secure market access for their products, several manufacturers have abandoned potentially promising projects, selectively focused on the more mature markets, or chosen to commercialize their technologies in unregulated segments, ultimately preventing the formation of a mature digital medical device market.

All jurisdictions are therefore striving to find the **right balance between robust assessment and flexible arrangements** that support, rather than stifle, innovation by DHTs. Assessment frameworks coupled with reimbursement pathways are beginning to blossom, with European countries such as Germany, Belgium, and France leading the way and several others poised to follow in their footsteps, all united by the need to test innovative solutions and drive the digital health revolution forward.

Insights from CERGAS research

CERGAS has devoted considerable effort to developing a research area focused on the assessment of DHTs and the evolving landscape of regulatory pathways and reimbursement frameworks. Our contribution has focused on multiple key domains. The first is related to the identification of **distinctive challenges in the assessment of DHTs**, particularly those subsets that meet the medical device definition and are therefore subject to market approval. A list of reasons that distinguish DHTs from conventional medical devices and that should characterize their value assessment is outlined in a special report published in Expert Review of Pharmacoeconomics & Outcomes Research. This finding is the result

of COMED, an EU-funded Horizon 2020 project led by CERGAS between 2018 and 2021. First, all DHTs evolve rapidly and can be adjusted based on their real-world performance, positioning themselves in a perpetual beta state that never seems to reach a stationary point. The limited production and scalability constraints of software have an impact on market configuration, as continuous technological evolution tends to significantly shorten the lifecycle of products in this segment. At the same time, they affect the process of generating clinical evidence, as traditional study designs such as randomized controlled trials are inadequate for evaluating the adaptive nature of DHTs and the multitude of potential mechanisms of change they may incorporate as part of their interventions. Additionally, DHTs introduce innovative endpoints that can be used for the first time to evaluate the therapeutic and economic benefits of other technologies. Second, DHTs are often fully interactive technologies whose effectiveness depends not only on the software itself but also on how it is used. This is particularly relevant given that many DHTs are directly managed by the patients themselves, possibly with the support of their caregivers, making the relationship between technology uptake and outcomes especially complex to predict and often non-linear. It is also well known that effective levels of engagement with DHTs not only vary from individual to individual, but are also extremely challenging to maintain over time, as use of DHTs tends to wane after initial enthusiasm. Third,



THE PROJECT

CERGAS actively participates in the activities of the European Task Force for Harmonized Evaluation of Digital Medical Devices (DMDs) and currently chairs its External Advisory Board, the body who contributes to the final recommendations by sharing real-world examples and perspectives from various stakeholders.
In the context of the Task Force, CERGAS researchers have studied the landscape of assessment and reimbursement frameworks adopted by policy-makers across the 27 EU Member States. Five clusters of prevailing approaches were identified, led by countries with national frameworks that combine regulation and reimbursement. Germany was the first to introduce a regulatory framework for the assessment and reimbursement of digital health applications (DiGAs), allowing clinicians to prescribe these apps after a thorough evaluation and subsequent publication in an online directory. France and Belgium also belong to this frontrunner group. Other clusters include countries that have yet to launch reimbursement pathways, but have introduced assessment frameworks, supervised institutional certification processes to guide individual behaviors, or are in the process of launching a national framework. Italy, for example, established a parliamentary intergroup in 2023 to accelerate the introduction of a national pathway for digital therapeutics.
Our analyses revealed considerable learning effects emerging across countries, thanks to formal and informal exchange opportunities, and contamination with academic recommendations. This should expedite the harmonization process, consequently increasing the attractiveness for manufacturers and accelerating the implementation of a single market for DHTs in the European Union.

DHTs are complex to evaluate because they often have broader organizational implications than any other medical technology. DHTs must be integrated into care pathways, with consistent organizational implications that require context-specific change management processes. As a result, the impact of implementing DHTs is often dependent on the specific organizational culture and routine, significantly limiting the transferability of evidence across organizations.

Not surprisingly, given these challenges, the **clinical evidence supporting DHTs is often suboptimal**, further complicating effective decision-making. A systematic review conducted by CERGAS researchers, which analyzed 69 experimental studies of mobile apps for the management of chronic diseases such as diabetes, cardiovascular disease, chronic respiratory disease and cancer, found that the quality of evidence was relatively low and that most studies tended to have a high risk of bias in the way they were conducted. Methodological problems associated with trials of DHTs include frequently small sample sizes, insufficient follow-up to observe benefits, and consistent dropout rates, which make it difficult to implement the intervention correctly and reduce the statistical power of analyses. Besides additional methodological guidance from researchers, to determine whether trial results truly reflect the benefits of apps or are merely a biased estimate, more focus should be placed on the development phase of DHTs using user-centered design and other participatory approaches to maximize the retention observed in the real world.

Regardless of the inherent challenges of evaluation and shortcomings in evidence generation, policy-makers are seeking to define assessment frameworks that link to coverage and reimbursement decisions and ensure a robust pathway for access to DHTs. To date, we observe a lack of multidimensional assessment frameworks suitable for use in Health Technology Assessment (HTA), a systematic and multidisciplinary evaluation process aimed at supporting policy makers with evidence-based information.

CERGAS has actively contributed to this debate by offering principles and guidelines for the development of assessment frameworks that are compatible with regulatory and HTA purposes and suitable for informing policy decisions. The definition of a clear and dynamic taxonomy based on key functions and risk levels is essential to guide effective decision-making on DHTs. Ad-hoc evidence requirements should then be associated with each of these categories, covering a wide range of outcome domains. In this regard, DHTs are expected to provide a **broad range of benefits**, complementing patient-centered health outcomes with novel domains related to the integration of care processes among healthcare providers, the influence of patient empowerment, autonomy, and the impact on environmental sustainability. Furthermore, DHTs are expected to improve access to care and reduce inequalities. Multidimensional assessment frameworks should therefore evaluate the impact of DHTs on equity to ensure that digital innovation supports progress towards equitable access to care, rather than exacerbating existing inequalities.

Harnessing the full potential of DHTs is a complex and challenging endeavor for policy-makers and regulators particularly in the realm of **digital therapeutics (DTx)**. One of the primary difficulties lies in the lack of a clear, unified definition of DTx, which occupy a gray area between pharmaceuticals and medical devices. On one hand, DTx resemble drugs in terms of the expected therapeutic effects and the rigorous evidence required to support their efficacy. On the other hand, they function as software, aligning them with medical devices. This duality complicates their classification, regulation, and integration into healthcare systems. CERGAS has been actively engaged in addressing these challenges through its dedicated research initiatives, particularly within the LIFT Lab. The research conducted on DTx indicates that after a peak in investment in 2021,

A systematic review conducted by CERGAS researchers has shown that most studies of mobile apps for the management of chronic diseases tended to have a high risk of bias in the way they were conducted. To learn more, see the paper linked above.

Adopting an integrative approach – one that takes into account the expectations of all stakeholders – is critical to overcoming the complexities and challenges that currently hinder the widespread adoption of DTx, as emphasized in the video linked above.

particularly in areas such as musculoskeletal diseases, mental and neurodevelopmental disorders, and metabolic diseases, interest for DTx has cooled, possibly also due to the regulatory uncertainty linked to these technologies. As emphasized in the accompanying video, improving, through our research projects, the understanding of the expectations of regulators, tech developers and companies but also patients and HCPs about DTx has the potential to ensure that the development and assessment of DTx proceed in a more coordinated and effective manner. This integrative approach is critical to overcoming the complexities and challenges that currently hinder the widespread adoption of DTx.

As national and regional solutions for integrating DHTs into care pathways continue to emerge, it is imperative **to prevent fragmentation and maximize collaboration.** In response to interest expressed by several EU Member States, the European Task Force for Harmonized Evaluation of Digital Medical Devices was established in 2022 to standardize evaluation procedures and promote collaborative solutions to these outstanding challenges.

Overall, the research projects conducted at CERGAS alert policy-makers of the need to adapt assessment frameworks and standards developed for traditional healthcare technologies to the peculiarities of DHTs. Our work also proposes pragmatic approaches for the assessment of DHTs that ensure flexibility and adaptability while maintaining rigor in adopted methodologies.

KEY MESSAGES TO POLICY-MAKERS

SET ANOTHER PLACE AT THE TABLE	Value the diversity of expertise in the ecosystem by engaging manufacturers, the scientific community, providers, and end users
HARMONIZATION IS KEY	Establish common standards and frameworks for evaluating DHTs, facilitating the transfer of ideas and solutions across different jurisdictions
FIND VALUE	Make decisions based on the overall value of DHTs, using a multidimensional approach that considers all areas that may be impacted by the introduction of DHTs
BE STRATEGIC	Define, update, and validate a strategy to support the adoption and implementation of DHTs across healthcare systems and settings
BUILD CAPACITY FROM THE INSIDE OUT	Develop a competency framework for HCPs, healthcare managers and technology procurement heads to guarantee selective uptake and implementation of DHTs

Remember: Decision-making on DHTs is complex, and major challenges require extensive collaboration

KEY MESSAGES TO DEVELOPERS AND MANUFACTURERS

IT ALL STARTS WITH PARTICIPATORY DESIGN	Improve the chances that your solutions will be valuable by involving all relevant stakeholders in their design and ensuring that they are driven by real needs, not technological progress
NO EVIDENCE, NO GO	Develop lifecycle evidence generation plans to ensure that DHTs are associated with robust evidence of benefit from the outset
OPPORTUNITIES MULTIPLY WHEN SEIZED	Engage with policy-makers throughout the decision-making process, taking advantage of pre-determined consultation opportunities and creating additional opportunities to actively contribute to change

Remember: A DHT that brings high value to someone who needs it will always be essential

Conclusions

Digital transformation is a pivotal trend in healthcare, impacting all facets of the healthcare ecosystem and a multiplicity of care settings. It promises to revolutionize the way healthcare services are delivered, offering numerous opportunities and developments that are increasingly within reach.

This ebook breaks down the process of digital transformation into three major trajectories, each showing different nuances. At the micro level, DHTs are contributing to reshaping patient-physician relationships and require ad-hoc prerequisites to be enacted for this transformation to take place. At the organizational level, healthcare managers are committed to defining strategies and practices to adapt their organizations to digital advancements. At the macro level, policy-makers are shaping novel regulations and frameworks to facilitate market access to DHTs based on robust evidence.

The pages of this ebook have highlighted the multifaceted ways in which **CERGAS** has been contributing to each of these transformations through its research and projects. As a research center, CERGAS is involved in this endeavor at several different levels. We provide all relevant stakeholders with the necessary evidence to inform their decisions and orient their behaviors. Furthermore, we directly support them in the field of implementing digital transformation and spread the necessary competencies through various educational initiatives. This work underscores all these activities, which are driven by a large group of researchers employing several disciplinary lenses and methodologies.

Above all, CERGAS's overarching ambition in the digital transformation of health care is to be recognized as a **catalyst for change** and to act as a platform able to generate a **learning community** around digital health and bridge different perspectives and stakeholders within the digital health ecosystem. Through this ambitious commitment and our efforts, we strive to realize the full potential of digital transformation, ensuring sustainable healthcare systems and the realization of tangible benefits for all stakeholders involved.

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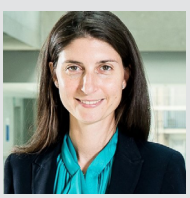

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